

Remarks

Claims 1-8, 13, 17-23 and 28 are pending. Claims 1 and 17 have been amended to provide that the dosage form has a distinct underlying compressed core and a shell portion as described in the paragraph bridging pages 2 and 3 and elsewhere. The claims refer to overcoat, rather than underlying for clarity purposes to describe that the shell is provided over the compressed core. No new matter has been added.

The Examiner rejects claims 1-13, 17-23 and 28 under 35 U.S.C. 103 as being unpatentable over U.S. Patent No. 4,808,413 (“Joshi et al.”) in view of U.S. Patent No. 5,190,927 (“Chang et al.”) and U.S. Patent No. 5,840,334 (“Raiden et al.”). Applicants respectfully traverse this rejection.

Claim 1 is now directed to dosage form comprising a compressed core and an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a water soluble polymer having a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum. Claim 17 is now directed to a dosage form comprising a compressed core and an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a water soluble polymer having a cloud point from about 20 to about 90° C, 5 to 40 weight percent of one or more carrageenans, and 0.5 to 30 weight percent lubricant.

The Examiner asserts that Joshi discloses a beadlets comprising an active ingredient and a binder, including hydroxypropylmethyl cellulose. The Examiner further asserts that further hydrocolloids, such as carrageenan and lubricants can be used. The Examiner cites Chang as showing the use of deacylated gellan gum to produce elastic gels having low brittleness. The Examiner then concludes that it would have been obvious to incorporate the gellan gum, as taught in Chang, into the beadlets of Joshi to achieve the beneficial effect of modifying its flexibility.

Applicants reiterate that the gellan gums taught in Chang are contemplated for use in “food gelling and thickening applications, including but not limited to confections, jams and

jellies, fabricated foods, water-based gels, pie fillings and puddings, pet foods, icings and frostings, and dairy products.” Column 2, lines 64-68. The beadlets shown in Joshi are not liquids or gels of any form. These beadlets are produced by spheronization to be placed in hard shell capsules or compressed into tablet. These beadlets are at the very least solid. The beadlets in Joshi are not used in a manner analogous to the compositions shown in Chang. There is absolutely no basis for incorporating a component shown in Chang intended to improve the characteristics of a gel into a solid spherical beadlet. There is absolutely no evidence that the gellan gum in Chang would have any beneficial effects on a solid beadlet as taught in Joshi. Hence, there is no basis for combining the references cited by the Examiner.

The independent claims have been amended to provide a clear distinction between the core and the shell portions of the dosage form. The hydrocolloid/HPMC components in Joshi that are referenced by the Examiner are described relative to what could be considered a core (though not compressed), while an optional overcoat can be provided. The Examiner alleges that the gellan gum of Chang could be added generally to the dosage form in Joshi. The Examiner does not indicate whether the addition is meant to be in the “core” or the optional overcoating. In view of the amendments above to clearly distinguish between the core and the shell of the dosage form, it is not proper to modify the overall dosage form in Joshi by adding the gellan gum in Chang to the optional overcoat and such a modification would not disclose the claimed invention.

The Examiner has failed to make a prima-facie showing of obviousness. Applicants request that the Examiner reconsider and withdraw his obviousness rejection based on Joshi, Chang and Raiden.

Serial No. 10/695,347

Applicants submit that the present application is now in condition for allowance. In the event that minor amendment will further prosecution, Applicants request that the Examiner contact the undersigned representative.

Respectfully submitted,

By: /David R. Crichton/
David R. Crichton
Reg. No. 37,300

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6131